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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,192	03/01/2002	David W. Morris	PP23696.0001/20366-035001	7201
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Novartis Vaccines and Diagnostics, Inc. Corporate Intellectual Property P.O. BOX 8097 EMERYVILLE, CA 94662-8097			EXAMINER	
			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1643	
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		05/30/2008	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/087,192	<b>Applicant(s)</b> MORRIS ET AL.
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 03 October 2007.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 11,21,22 and 24-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 11, 21, 22 and 24-40 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/1648)  
Paper No(s)/Mail Date 03/05/2008

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendments and Argument***

1. Claims 11, 21, 22 and 24-40 are pending.

Claims 10, 20 and 23 are cancelled.

Claims 11, 21, 22, 24, 25, 27, 24, 35 and 38 have been amended.

Claims 39 and 40 have been added.

Claims 11, 21, 22 and 24-40 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Information Disclosure Statement***

3. The Examiner appreciates and acknowledges Applicants' submission of the remaining thirteen references not considered and listed on the information disclosure statement (IDS) filed October 31, 2003. The IDS submitted October 9, 2007 lists several references with no dates. Applicants must note the dates of publication for references AA, AH, AI and AJ. While the references have been considered the IDS continues to to comply with 37 CFR 1.98(a)(2). Applicants should also provide dates of the references listed therein.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 11, 21, 22 and 24-38 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing bladder carcinoma, colon cancer, breast cancer or prostate cancer comprising detecting evidence of differential expression of sialophorin gene (SEQ ID NO: 1175) in a patient sample, wherein evidence of differential expression is detected by measuring the level of an expression product of sialophorin and wherein the expression product is a mRNA having a sequence of SEQ ID NO: 1175, does not reasonably provide enablement for the said method measuring a full complement of the mRNA sequence of SEQ ID NO: 1175 (sialophorin) has been withdrawn in light of Applicants' amendments to the claims. Claims 10, 20 and 23 have been cancelled.

5. The rejection of claims 11 and 34-38 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Claim 23 has been cancelled.

6. The rejection of claims 11, 21 and 24-38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn. Claims 10, 20 and 23 have been cancelled.

***Claim Rejections - 35 USC § 102***

7. The rejection of claim 10 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2007/0037165 A1 (effective filing date September 8, 2000) is withdrawn.

8. The rejection of claims 10, 20 and 23 Claims under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001) has been withdrawn in view of the cancellation of claims.

9. The rejection of claims 11, 21, 22 and 24-38 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2006/0194265 A1 (effective filing date February 27, 2002) has been withdrawn. Claims 10, 20 and 23 has been cancelled.

***New and Maintained Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

10. Claims 11, 21, 22 and 24-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***THIS IS A NEW MATTER REJECTION.***

Applicants claim a method for diagnosing several types of cancer, as well as the broadly termed carcinoma comprising detecting differential expression of sialophorin, wherein the sialophorin gene expression is up-regulated or increased 50%-150% relative to the control. However, this claimed method wherein the level of expression is increased and indicates any particular cancer is not set forth in the specification. Page 26, lines 33-35 of the specification note a cancer phenotype can be detected, which is not the same as detecting a particular sequence and ascribing it to a particular cancer type. While detecting expression profiles of cells in different states is contemplated there seems to be insufficient contemplation for the up-regulation of sialophorin in a sample corresponds to any particular cancer.

SEQ ID NO: 1175 is mentioned in the specification in the context of several methods, however not as claimed, wherein colon, breast or prostate cancer is definitively diagnosed. The specification does disclose carcinoma associated (CA) nucleic acids can be up-regulated, as well as down-regulated in carcinomas in carcinomas, however there seems to be insufficient disclosure for SEQ ID NO: 1175 is regulated in any particular cancer, see page 26. Applicants are requested to pointedly express where in the specification by page and section support for this claimed invention can be found or delete the new matter.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 39 is vague and indefinite in the recitation "...hybridizes under highly stringent conditions...". While a suggested example of hybridization conditions is provided in paragraph bridging pages 11 and 12 of the specification this example is not non-limiting and the metes and bounds of the hybridization conditions are not clear.

***Claim Rejections - 35 USC § 102***

13. The rejection of claims 11, 21, 22 and 24-38 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0038207 A1 (filed September 14, 2001) is maintained.

Applicants aver the publication teaches "...expression of over 3400 genes in normal urothelium to expression in bladder tumor samples at various stages" and does not correlate the level of sialophorin to the presence of colon, breast or prostate cancer, see Remarks, page 9, Rejections...section. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants have identified SEQ ID NO: 1175 as human sialophorin. Consequently, the disclosed sialophorin of the patent application publication is the same as Applicants' SEQ ID NO: 1175. The publication discloses evaluating assays, which may be used to assess gene expression patterns wherein patient samples are assayed, see page 1, sections 0017 and 0018; and page 4, sections 0056-0058. Given the

sialophorin is the same as that claimed and the patient sample listed in the claims is not limited, as well as the active method steps are the same, the prior art reads on detection of colon, breast and prostate cancer.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
27 May 2008

/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643

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